K072164
SEP - 5 2007

Exhibit B 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned 510(k) number is: _____.

1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Tel: +86 755 2658 2888
Fax: +86 755 2658 2680

Contact Person:
Li Dongling
Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: Jun 21, 2007

2. Device Name: DC-6 Diagnostic Ultrasound System

Classification
Regulatory Class: II
Review Category: Tier II
21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)
21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)
21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

3. Marketed Device:

The subject device is substantially equivalent in its technologies and functionality to the original DC-6 Diagnostic Ultrasound System that is already cleared under premarket notification number K063500, and other predicate devices noted below:

0045

Predicate Device	Manufacturer	Model	510(k) Control Number
First	Toshiba	NEMIO SSA-550A	K010631
Second	Aloka	SSD-5000	K012080
Third	Philips	iU22	K042540
Fourth	Hewlett Packard	Sonos 5500	K990339
Fifth	Philips	HD11	K062247
Sixth	GE	Logiq 9	K061129

4. Device Description:

The DC-6 Diagnostic Ultrasound System is a general purpose, mobile, software controlled, ultrasound diagnostic system. Its function is to acquire and display ultrasound mages in B-Mode, M-Mode, Color mode, PW mode, CW mode, Power/DirPower mode or the combined mode (i.e. B/M Mode). This system is a Track 3 device that employs an array of probes that include linear array, phased array and convex array with a frequency range of approximately 2 MHz to 12 MHz. The modified DC-6 Diagnostic Ultrasound System also provides Smart3D imaging (Free hand 3D), iScape imaging (panoramic imaging) and Free Xros M imaging (anatomic M).

5. Intended Use:

The device is intended for use by a qualified physician for ultrasound evaluation of abdominal, cardiac, small parts (breast, testes, thyroid, etc.), peripheral vascular, fetal, transrectal, transvaginal, pediatric, neonatal cephalic, musculoskeletal (general and superficial), Urology/Prostate and intraoperative (liver, gallbladder, pancreas).

6. Safety Considerations:

The DC-6 Diagnostic Ultrasound System has been tested as Track 3 Device per the FDA Guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued September 1997. The acoustic output is measured and calculated per NEMA UD 2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment: 2004 and NEMA UD 3 Output Display Standard. The device conforms to applicable medical device safety standards, such as IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37 and ISO 10993-1.

Conclusion:

The conclusions drawn from testing of the DC-6 Diagnostic Ultrasound System

demonstrate that the device is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2007

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
% Mr. Robert Mosenkis
President
Citech
5200 Butler Pike
PLYMOUTH MEETING PA 19462-1298

Re: K072164
Trade Name: DC-6 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, IYN and ITX
Dated: August 3, 2007
Received: August 6, 2007

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the DC-6 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

7LT4	6LE7	3C5A
2P2	7L4A, 7L6, 10L4	
6LB7	6C2	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device

can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Mr. Paul Hardy at (240) 276-3666.

Sincerely yours,

for NCB

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

System × Transducer _____

Model: DC-6

510(k) Number(s) _____

Clinical Application	Mode of Operation									
	A	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P		P	Note 1, 2, 4
Abdominal		P	P	P		P	P		P	Note 1, 2, 3,4
Intraoperative (specify)*		N	N	N		N	N		N	Note 2, 3, 4
Intraoperative Neurological										
Pediatric		P	P	P		P	P		P	Note 1, 2, 3,4
Small organ(specify)**		P	P	P		P	P		P	Note 2, 3, 4
Neonatal Cephalic		P	P	P		P	P		P	Note 2, 3, 4
Adult Cephalic										
Cardiac		P	P	P	N	P	P		P	Note 1, 4
Transesophageal										
Transrectal		P	P	P		P	P		P	Note 2, 4
Transvaginal		P	P	P		P	P		P	Note 2, 4
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P		P	Note 2, 3, 4
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		P	Note 2, 3, 4
Musculo-skeletal Superficial		P	P	P		P	P		P	Note 2, 3, 4
Other (specify)***		N	N	N		N	N		N	Note 1, 2, 4

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Small organ-breast, thyroid, testes, etc.

**Intraoperative includes abdominal, thoracic, and vascular etc.

***Other use includes Urology/Prostate.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: Free Xros M imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072164

JUL 25 2007

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer ×

Model: 7LT4

510(k) Number(s) _____

Clinical Application	Mode of Operation									
	A	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N		N	Note 2, 3, 4
Intraoperative (specify)*		N	N	N		N	N		N	Note 2, 3, 4
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N	Note 2, 3, 4
Small organ(specify)**		N	N	N		N	N		N	Note 2, 3, 4
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N	Note 2, 3, 4
Laparoscopic										
Musculo-skeletal Conventional		N	N	N		N	N		N	Note 2, 3, 4
Musculo-skeletal Superficial		N	N	N		N	N		N	Note 2, 3, 4
Other (specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Small organ-breast, thyroid, testes, etc.

**Intraoperative includes abdominal, thoracic, and vascular etc.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: Free Xros M imaging

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

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(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072164

JUL 25 2007

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer X

Model: 2P2

510(k) Number(s) _____

Clinical Application	Mode of Operation									
	A	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)*										
Intraoperative Neurological										
Pediatric										
Small organ(specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N	N	N		N	Note 1, 4
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Urology)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Small organ-breast, thyroid, testes, etc.

**Intraoperative includes abdominal, thoracic, and vascular etc.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: Free Xros M imaging

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072164

JUL 25 2007

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer ×

Model: 6LB7

510(k) Number(s) _____

Clinical Application	Mode of Operation									
	A	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)*										
Intraoperative Neurological										
Pediatric										
Small organ(specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N		N	N		N	Note 2, 4
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)***		N	N	N		N	N		N	Note 2, 4

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Small organ-breast, thyroid, testes, etc.

**Intraoperative includes abdominal, thoracic, and vascular etc.

***Other use includes Urology/Prostate.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: Free Xros M imaging

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072164

JUL 25 2007

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer X

Model: 6LE7

510(k) Number(s) _____

Clinical Application	Mode of Operation									
	A	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N		N	Note 2, 4
Abdominal		N	N	N		N	N		N	Note 2, 5
Intraoperative (specify)*										
Intraoperative Neurological										
Pediatric										
Small organ(specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N		N	N		N	Note 2, 4
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)***		N	N	N		N	N		N	Note 2, 4

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Small organ-breast, thyroid, testes, etc.

**Intraoperative includes abdominal, thoracic, and vascular etc.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: Free Xros M imaging

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K072164

JUL 25 2007

Diagnostic Ultrasound Indications for Use Form

System ___ Transducer X

Model: 7L4A, 7L6, 10L4

510(k) Number(s) _____

Clinical Application	Mode of Operation									
	A	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)*										
Intraoperative Neurological										
Pediatric										
Small organ(specify)**		E	E	E		E	E		E	Note 2, 3, 4
Neonatal Cephalic		E	E	E		E	E		E	Note 2, 3, 4
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		E	E	E		E	E		E	Note 2, 3, 4
Laparoscopic										
Musculo-skeletal Conventional		E	E	E		E	E		E	Note 2, 3, 4
Musculo-skeletal Superficial		E	E	E		E	E		E	Note 2, 3, 4
Other (specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Small organ-breast, thyroid, testes, etc.

**Intraoperative includes abdominal, thoracic, and vascular etc.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: Free Xros M imaging

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

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(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072164

JUL 25 2007

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer X

Model: 6C2

510(k) Number(s) _____

Clinical Application	Mode of Operation									
	A	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N		N	Note 2, 4
Intraoperative (specify)*										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N	Note 2, 4
Small organ(specify)**										
Neonatal Cephalic		N	N	N		N	N		N	Note 2, 4
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Small organ-breast, thyroid, testes, etc.

**Intraoperative includes abdominal, thoracic, and vascular etc.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: Free Xros M imaging

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072164

JUL 25 2007

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer X

Model: 3C5A

510(k) Number(s) _____

Clinical Application	Mode of Operation									
	A	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E	E		E	E		E	Note 1, 2, 4
Abdominal		E	E	E		E	E		E	Note 1, 2, 4
Intraoperative (specify)*										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N	Note 1, 2, 4
Small organ(specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Urology)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Small organ-breast, thyroid, testes, etc.

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Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: iScape

Note 4: Free Xros M imaging

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Prescription USE (Per 21 CFR 801.109)

Nancy C Brogdon

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Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072164